UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL], **Plaintiffs,** **v.** **[UNDER SEAL],** **Defendants.**	**Civil Action No.** **AMENDED COMPLAINT AND JURY DEMAND** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

FILED UNDER SEAL

NOT TO BE FILED

ON PACER

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* SHANTAE M. WYATT and LATOYA SPARROW, **Plaintiffs,** **v.** **BIOTEK REMEDYS, INC., VALUSTAR PHARMACY, LLC, AZBDBR, LLC (d/b/a "AVASARX PHARMACY"), CHAITANYA R. GADDE, CARLA SPARKLER and DAVID TABBY, D.O.** **Defendants.**	**Civil Action No. 19-cv-06069-PD** **AMENDED COMPLAINT AND JURY DEMAND** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

Qui Tam Relators Shantae M. Wyatt and Latoya Sparrow, by and through counsel, Kessler Topaz Meltzer & Check, LLP, on behalf of the United States of America, bring this Amended Complaint against Defendants Biotek Remedys, Inc. ("Biotek"), Valustar Pharmacy, LLC ("Valustar"), AZBDBR, LLC ("AvasaRx Pharmacy"), (collectively, "the Pharmacies""), Chaitanya R. Gadde, Carla Sparkler (collectively, with the Pharmacies, "the Biotek Defendants") and David Tabby, D.O. and allege based on direct and independent knowledge:

I. INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America arising from false and fraudulent records, statements, and claims made, used and caused to be made, used, and presented by Defendants and/or their agents, employees, predecessors and co-conspirators, in violation of the federal False Claims Act, 31 U.S.C. § 3729

et seq., ("FCA") and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)("Anti-Kickback Statute" or "AKS").

2. Defendants defrauded federally-funded health insurance programs, including Medicare.

3. This scheme arises from the Biotek Defendants' primary business of selling and administering expensive, infusion drugs and biologics for the treatment of complex disease states, including cancer, autoimmune and inflammatory disorders.

4. Specifically, the Biotek Defendants knowingly and unlawfully induced beneficiaries of federally funded health care programs to utilize, and rewarded them for utilizing the Pharmacies. The Biotek Defendants effectuated this scheme by paying kickbacks to beneficiaries through routine waiver of mandated federal cost-sharing obligations without regard to authenticated financial need. The cost-sharing obligations waived by the Biotek Defendants were often in amounts exceeding several thousand dollars per beneficiary.

5. The Biotek Defendants further violated the AKS by inducing physicians, including Defendant Tabby, to refer beneficiaries to the Pharmacies by, among other ways, waiving beneficiary cost-sharing amounts; providing referring physicians and medical practices with expensive meals and entertainment; and providing free administrative, clinical and insurance support services.

6. As a result, claims submitted by the Pharmacies and Defendant Tabby to federal health care programs were false in that they were submitted in violation of the federal AKS.

7. The Biotek Defendants' scheme further entailed reporting, and causing to be reported, false and fraudulent statements regarding the out-of-pocket expenditures paid by federal health care program beneficiaries. In so doing, upon information and belief, the Biotek Defendants

increased costs to the Medicare system, including by hastening the point at which Medicare Part D beneficiaries emerged from the coverage gap into catastrophic coverage, which is substantially more costly to the Medicare program.

8. The Biotek Defendants also overbilled Medicare and other federally funded healthcare programs for infusion products above the allowable amount for what was ordered, including at times billing double or triple the amount of what was provided to the patient.

9. As a result of these fraudulent practices, Defendants submitted and caused the submission of false claims to Medicare.

II. JURISDICTION AND VENUE

10. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular, the FCA. In addition, the FCA specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b).

11. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and Defendants have sufficient minimum contacts with the United States of America.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Defendants have transacted business in this District.

13. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint has been filed in camera and will remain under seal for a period of at least 60 days and shall not be served on Defendants until the Court so orders.

14. Pursuant to 31 U.S.C. § 3730(b)(2), Relators have served copies of the original and amended Complaint upon the, United States Attorney for the Eastern District of Pennsylvania, and upon, Attorney General of the United States,

15. No allegation set forth in this Complaint is based upon prior public disclosures (31 U.S.C. § 3730(e)(4)(A)) of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit, or investigation, or in a Government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

16. To the extent that there has been a public disclosure, Relators are the original sources of those allegations within the meaning of the False Claims Act. 31 U.S.C. § 3730(e)(4)(B).

III. THE PARTIES

17. Plaintiff, the United States of America on behalf of its agency, the United States Department of Health and Human Services ("HHS") and its Centers for Medicare and Medicaid Services ("CMS"), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. ("Medicare"), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42. U.S.C. §§ 1396 et seq. ("Medicaid").

18. Relator Shantae M. Wyatt is a resident of the State of Delaware and a citizen of the United States. Relator Wyatt was employed by Defendant Biotek in the Reimbursement Department from April of 2018 until October 2019. In July 2018, Relator Wyatt transitioned from Reimbursement Specialist to a new position as Lead Reimbursement Specialist. In December 2018, Relator Wyatt assumed the position of Reimbursement Department Manager. In these positions, Relator Wyatt oversaw the Reimbursement Department and analyzed and reconciled claims for health care services provided by the Pharmacies, including claims submitted to Medicare.

19. Relator Latoya Sparrow is a resident of the State of Delaware and a citizen of the United States. From March 2018 to September 2019, Relator Sparrow was employed by

Defendant Biotek as a Reimbursement Specialist. In this position, Relator Sparrow analyzed and reconciled claims for health care services provided by the Pharmacies, including claims submitted to Medicare.

20. Defendant Biotek is a Delaware corporation, located at 2 Penns Way, Suite 404, New Castle, DE 19720-2407. Defendant Biotek is a national, privately held specialty infusion pharmacy. Its National Provider Identification ("NPI") is 1689955163. Defendant Biotek is licensed as a pharmacy in a number of states, including Pennsylvania. Biotek provides specialty drugs, biologics and infusion services to hundreds of patients in Philadelphia.

21. Defendant Valustar Pharmacy, LLC is a Texas limited liability company located at 7227 Fannin Street, STE 103, Houston, Texas 77030. Defendant Valustar is a specialty infusion pharmacy affiliated with Defendant Biotek and is owned by Defendant Gadde. Its NPI is 1841650595.

22. Defendant AZBDBR LLC is a Delaware limited liability company operating in Arizona under the trade name AvasaRx Pharmacy (hereinafter, "AvasaRx Pharmacy"). AvasaRx Pharmacy is an Arizona specialty services pharmacy located at 816 N. 6th Avenue, Phoenix, Arizona 85003. Its NPI is 1740796093.

23. Defendant Chaitanya R. Gadde is a citizen of the State of Delaware. He is the founder, CEO, and co-owner of Defendant Biotek.

24. Defendant Carla Sparkler is a citizen of the State of Delaware. She is the Chief Marketing Officer ("CMO") of Defendant Biotek.

25. Defendant David Tabby, D.O., is a citizen of the State of Pennsylvania. He is a doctor of osteopathic medicine and the owner of Optimum Neurology, located in Bala Cynwyd, PA.

26. The Pharmacies—all specialty infusion pharmacies— provide expensive specialty drugs and biologics intended for individuals with complex, chronic disease states, including cancer, hemophilia, multiple sclerosis, rheumatoid arthritis, and other autoimmune and inflammatory disorders. The Pharmacies focus much of their business on providing specialty drugs to patients through continuous infusion therapy, which refers to the administration of a solution of medication intravenously, often over the course of several hours. The Pharmacies provide infusion therapy services in the home, while also operating a small infusion suite at each pharmacy. In this capacity, the Pharmacies operate as specialty infusion pharmacies.

27. Specialty pharmacies are distinct from traditional pharmacies in that specialty pharmacies provide medications requiring specialized handling, storage, and distributions for patients which complex disease states who require regular contact and clinical management by practitioners. Specialty drugs sold by specialty pharmacies are high-cost products utilized for certain therapies requiring specialized administration. Specialty drugs are among the costliest medications in the Medicare program and often require a beneficiary to pay thousands of dollars in annual out of pocket spending.

28. At all times relevant to this Complaint, the Pharmacies participated in federally funded health care programs by submitting claims for covered infusion products and services to federally funded health care programs, including through Medicare Part B and Medicare Part D.

29. During the relevant period, Defendant Biotek's internal financial statements reflected the consolidated revenues of Defendants Valustar and AvasaRx Pharmacy. Upon information and belief, the Pharmacies earned between $7 to 12 million dollars in revenue per month. Upon information and belief, more than 50% of the Pharmacies' revenue was derived from Medicare claims.

IV. APPLICABLE LAW

A. Federal False Claims Act

30. The federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, (the "FCA") provides, in pertinent part, that:

> Any person who …(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires [to do so] …[or] (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.
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> is liable to the United States Government for a civil penalty of not less than [$5,500] and not more than [$11,000] [as amended] … plus three times the amount of damages which the Government sustains because of the act of that person.

31. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information … (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required. *Id.* § 3729(b)(1).

32. The term "claim" is defined to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property," that is made to contractors and agents of federal government programs. 31 U.S.C. § 3729(b)(2). The term "claim" includes claims submitted to third-party sponsors for drugs covered under Medicare Part D. *See United States ex rel. Spay v. CVS Caremark,* 913 F. Supp. 2d 125, 150 (E.D. Pa. 2012).

B. The Anti-Kickback Statute

33. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration to induce a person (a) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or (b) to purchase, lease, order, arrange for or recommend any good facility, service or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) and (2).

34. Compliance with the AKS is expressly and impliedly required for reimbursement of Medicare claims, and claims made in violation of the law are actionable civilly under the False Claims Act. *See* 42 U.S.C. § 1320a-7b(g) (2010) (a "claim that includes items or services resulting from a violation of … [the AKS] constitutes a false or fraudulent claims for purposes of [the False Claims Act] …").

V. FACTUAL ALLEGATIONS

A. Medicare

35. The United States, through HHS, administers the Medicare program, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395 *et seq.* Medicare provides health insurance coverage for individuals over 65 years of age, individuals under 65 with certain disabilities, and individuals of any age with End-Stage Renal Disease. In 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act, which established Medicare Part D, a voluntary prescription drug coverage benefit for eligible individuals. *See* 42 U.S.C. §§ 1395w-101 *et seq.*; 42 C.F.R. § 423.

36. Medicare beneficiaries entitled to Medicare benefits under Medicare Part A (hospital insurance) or Medicare Part B (medical insurance) are eligible for prescription drug benefits under Part D. In general, drugs covered under the Part A or B benefit are not covered

under Part D. 42 U.S.C. § 1395w-102(e)(2)(B). Notwithstanding the creation of the Part D benefit, certain prescription drugs remain covered under Medicare Part B, including, for example, most injectable and infused drugs administered by a licensed medical provider, as well as drugs infused through an infusion pump. *See* 42 U.S.C. §§ 1395j-1395w-6.

37. Under Medicare Part B, the federal government contracts with private insurance companies, known as Medicare Administrative Contractors ("MACs") to handle payment for services in specific geographic areas. MACs act as fiscal intermediaries and are responsible for accepting Medicare claims, making coverage determinations, and making payments on claims.

38. To obtain payment for services they provide to Medicare beneficiaries, Medicare enrolled providers file claims with the MAC for their region.

B. Medicare Part D

39. Under Medicare Part D, coverage is not provided through the traditional Medicare program; rather, private entities, known as "Plan Sponsors," establish Part D benefit plans, with features that vary depending on certain factors. Plan Sponsors are required to submit the features of each Part D plan to CMS, which makes public the features of the plans, including the amount of applicable deductibles, co-insurance, co-payments and other potential out-of-pocket liabilities. 42 C.F.R. §§ 423.265 and 423.272. To obtain coverage under Part D, eligible Medicare beneficiaries must enroll in one of the Part D plans offered by Plan Sponsors.

40. During each year, on a monthly basis, CMS pays the Plan Sponsor estimated payments comprised of the Sponsor's direct premium subsidy per enrolled beneficiary, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329.

41. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. An individual is eligible to enroll in Medicare Part D if the

individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Medicare Part A or enrolled under Medicare Part B. *See* 42 C.F.R. § 423.30(a).

42. Plan D Sponsors, in turn, enter into subcontracts with pharmacies or other "downstream entities" to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

43. These entities submit claims to Part D plans that pay for the drug using funds provided by CMS from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

44. Plan Sponsors notify CMS throughout the plan year each time a Medicare beneficiary has a prescription filled under Part D. Claims are submitted to CMS through a Prescription Drug Event ("PDE") record for every prescription that is filled for a plan member. By providing this drug cost and payment data for each filled prescription, the Plan Sponsor informs CMS of the actual prescription drug costs.

45. At the end of the plan year, if CMS has underpaid the sponsor for low-income subsidies or reinsurance costs, CMS makes up the difference. If CMS overpaid the sponsor for these costs, it recoups the overpayment from the Part D sponsor. 42 C.F.R. § 423.343.

46. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines the risk-sharing amounts owned by plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages (commonly called the Part D "risk corridor") 42 U.S.C. § 1395w-115(e); 42 C.F.R. § 423.336.

47. Medicare requires that Part D Plan Sponsors agree to comply with the requirements and standards of Part D and all terms and conditions of payment. 42 U.S.C. §1395w-112(b)(1); 42 C.F.R. § 423.505(i)(4)(iv). These terms include compliance with "[f]ederal laws and regulations designed to prevent fraud, waste and abuse, including … the False Claims Act … and the anti-kickback statute …" 42 C.F.R. § 423.505(h)(1).

48. Further, the contract between the Part D Plan Sponsor and CMS must include those terms set forth in 42 C.F.R. § 423.505(b), including compliance with certain reporting requirements (*see* § 423.514) and claims submission (*see* § 423.505(b)(8) and (9)).

49. Compliance with regulatory requirements is similarly required of downstream entities, typically those entities that maintain a contract with the Part D Sponsor to provide the ultimate health care service rendered to the enrollee. *See Medicare Prescription Drug Benefit Manual*, ch. 9, § 40. Under CMS regulations, Sponsors' subcontracts with pharmacies must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. §§ 423.505(i)(3)(v) and 423.505(i)(4)(iv).

50. When a specialty pharmacy receives a prescription from a physician, the pharmacy confirms Part D coverage and plan details for the beneficiary, and dispenses the prescribed drugs to or for the benefit of the Medicare Part D beneficiary. The pharmacy then submits an electronic claim to the beneficiary's Part D Plan Sponsor (either directly or through a subcontracted intermediary). This electronic claim includes the cost of the drug, a dispensing fee, and any sales or similar taxes paid, less any payments received from the enrollee. As a condition of payment, sponsors, in turn must submit data and information necessary for CMS to effectuate Part D's payment provisions; this data includes the claims information provided by the specialty pharmacy

to the Plan Sponsor for use in submitting PDE's to CMS. 42 U.S.C. § 1395w-115(c)(1)(C); (d)(2); 42 C.F.R. § 423.322.

51. The pharmacy then receives payment from the Plan Sponsor for the costs not paid by the beneficiary. The pharmacy is responsible for collecting any cost-sharing portion from the Part D beneficiary.

52. The Part D Plan Sponsor, in turn, notifies CMS that a drug has been purchased and dispensed, by completing a Prescription Drug Event ("PDE") record, which details the amount paid to the pharmacy. As a condition of payment, the information must be certified to CMS by the Sponsor as accurate, complete and truthful. 42 C.F.R. § 423.505(k)(1). In making this certification to CMS, the Sponsor relies upon the accuracy and integrity of the underlying claim information. 42 C.F.R. § 423.505(k)(3). CMS utilizes the information in the PDE at the end of the payment year to reconcile annual sponsor costs with advanced payments that have been made to the sponsor by CMS. *See United States ex rel. Spay v. CVS Caremark*, 913 F. Supp. 2d 125, 150 (E.D. Pa. 2012).

C. Financial Responsibility of Medicare Enrollees

53. Federally funded health care programs utilize beneficiary cost-sharing measures that impose financial responsibility on the beneficiary for certain costs related to the services utilized. For prescription drugs covered under Part B, the beneficiary is typically responsible for 20% of the Medicare-approved amount, as well as the applicable Part B deductible.

54. Although the specific features may vary depending on the particular plan, Part D drug plans provide coverage in phases, with the amount of enrollee cost-sharing varying greatly depending on the phases of coverage. Coverage phases are determined by the amount of "true out-of-pocket" ("TrOOP") expenditures the enrollee has incurred on prescription medication during the calendar year.

55. Once an eligible enrollee selects a Part D plan, the enrollee begins paying monthly premiums to the Plan Sponsor, in accordance with the terms of the particular plan. When an enrollee obtains a prescription from a physician, the enrollee has the prescription filled by a pharmacy. The pharmacy confirms Part D coverage for the enrollee, as well as the amount of enrollee financial responsibility for the prescription.

56. Beyond the monthly premium, Part D coverage requires that beneficiaries maintain financial responsibility (also known as "cost-sharing") for:

a. an annual deductible;

b. a percentage-based coinsurance for actual costs above the annual deductible but at or below an initial coverage limit ("initial benefit");

c. a percent of the cost of brand name and generic drugs for the amount above the deductible plus the coinsurance (this feature of the Part D plans is commonly referred to as the "coverage gap" or "doughnut hole," and historically required beneficiaries to bear a larger percentage of the drug costs up to the annual out-of-pocket threshold.[1]

d. a percentage of catastrophic coverage ("Catastrophic Coverage") costs for the remainder of a coverage year once an enrollee's costs exceed the annual out-of-pocket threshold.

Sponsors maintain some degree of flexibility to offer plans that reduce cost-sharing obligations.

[1] The coverage gap was closed for brand name drugs in 2019, with beneficiaries responsible for no more than 25% of the cost of brand name drugs, with the manufacturer providing a discount of 70% on the drug, and the Medicare plan responsible for the remaining 5% of the cost. However, in 2019, beneficiaries in the coverage gap are still responsible for paying 37% of the cost of generic drugs (with Medicare responsible for the remaining 63%). The coverage gap will close for generic drugs in 2020.

57. There is no cap on the amount of coverage a beneficiary can receive under Catastrophic Coverage through the calendar year. Once the calendar year ends, however, the stages are reset and the beneficiary is once again responsible for the amounts correlating to the TrOOP stage.

58. Medicare additionally provides "Extra Help" benefit to pay prescription drug costs for those who meet specific income and resource limits. This benefit helps defray the cost of the monthly Part D premium, as well as other Part D out-of-pocket costs.

59. The correct calculation of TrOOP expenditures is an essential component of Part D plan administration and CMS has issued significant guidance on the TrOOP methodology, emphasizing the importance of accurate TrOOP reporting. *See, e.g., Medicare Prescription Drug Benefit Manual,* ch. 5, § 30. As with other aspects of the Part D program, responsibility for accurate reporting of TrOOP data to CMS falls upon the Part D Sponsor and downstream entities, including pharmacies. Indeed, PDE's specifically require the reporting of beneficiary payments, listing the dollar amount paid by the Part D beneficiary.

60. Further, CMS has specifically identified inaccurate TrOOP calculation as an example of potential fraud, waste and abuse in the Medicare Part D program. *Medicare Prescription Drug Benefit Manual,* ch. 9, § 50.6.9.

D. Waiver of Cost-Sharing Obligations

61. Routine waivers of beneficiary cost-sharing amounts, without regard to authenticated financial need, may constitute illegal remuneration under the Anti-Kickback Statute. Indeed, as early as 1994, the HHS Office of Inspector General issued a "Special Fraud Alert" regarding the unlawful practice of routinely waiving cost-sharing amounts to be paid by Medicare beneficiaries, because such practices can result in illegal inducements to beneficiaries and overutilization of healthcare items and services, in violation of the health care Anti-Kickback State.

59 Fed. Reg. 65373, 65374 (Dec. 19, 1994); *see* 42 U.S.C. § 1320a-7b(b). In identifying common patterns of fraudulent conduct, the OIG specifically listed marketing tactics stating, "Insurance Accepted as Payment in Full," and the routine use of "financial hardship" forms with no good faith attempt to determine the beneficiary's financial condition. 59 Fed. Reg. 65373, 65374 (Dec. 19, 1994).

62. The principles underlying the Special Fraud Alert have been applied in fashioning narrow statutory safe harbors that only permit waiver of cost-sharing obligations in extremely narrow circumstances, deemed to alleviate concerns of fraudulent inducements. Specifically, with regard to Medicare Part D programs, pharmacies may receive safe harbor protection under the AKS for waivers of cost-sharing amounts, only where the person making the waiver (i) does not offer the waiver as part of any advertisement or solicitation; (ii) except for subsidy eligible individuals, as defined in 42 U.S.C. § 1395w-114, does not routinely waive coinsurance or deductible amounts; and (iii) except for subsidy eligible individuals, as defined in 42 U.S.C. § 1395w-114, determines in good faith that the recipient of the waiver is in financial need or fails to collect the owed amount after reasonable collection efforts. *See* 42 U.S.C. § 1320a-7b(b)(3)(G); 42 C.F.R. § 1001.952(k)(3); *See also Medicare Prescription Drug Benefit Manual*, ch. 5, § 30.4. The safe harbor applies not only to waivers of Part D cost-sharing, but also to all federal healthcare programs and includes Part B and Medicaid. 42 C.F.R. § 1001.952(k)(3).

63. The safe harbor does not protect waiver of cost-sharing that is "characterized as a 'cost-saving program'… [or] waivers that are advertised as part of a 'program' to waive copayments." 81 Fed. Reg. 88368, 88372 (Dec. 7, 2016).

E. Defendants' Fraudulent Scheme

64. As specialty infusion pharmacies, the Pharmacies provided expensive specialty drugs for intravenous infusion to patients and contracted with home health nursing agencies to administer the infusion drugs to patients in their homes.

65. The expensive infusion products provided by the Pharmacies include: intravenous immune globulin ("IVIG") Gamunex-C, for the treatment of an array of autoimmune and inflammatory disorders; Rituxan, the trade name for rituximab, and Humate P for the treatment of hemophilia; Xenazine, for treatment of chorea (involuntary movements) associated with Huntington's disease patients; and, Remicade, the trade name for infliximab, for the treatment of rheumatoid arthritis ("RA") and other autoimmune disorders.

66. The Biotek Defendants operated a scheme to defraud federal and state healthcare programs by paying kickbacks to beneficiaries and referring physicians in the form of routine waiver of cost sharing amounts, to induce the use of specialty drugs and services provided by the Pharmacies and the referral of patients to receive infusion products and services from the Pharmacies. These kickbacks frequently exceeded thousands of dollars per beneficiary. The Biotek Defendants further paid kickbacks to referring physicians and their practices in the form of expensive meals, entertainment and free administrative, clinical and insurance support, to induce referrals.

67. In March 2018, Relator Sparrow was hired by Defendant Biotek as a Reimbursement Specialist. One month later, in April 2018, Relator Wyatt was hired as Reimbursement Specialist, and subsequently assumed the roles of Lead Reimbursement Specialist and Reimbursement Manager. In these roles, Relators managed the Pharmacies' accounts receivables and analyzed and reconciled claims submitted for health care services provided by the Pharmacies, including claims submitted to Medicare.

68. As part of their regular employment in the Reimbursement Department, Relators maintained access to the Biotek Defendants' CPR+ computer system, including access to records pertaining to events that preceded Relators' employment at Biotek.

69. The Biotek Defendants maintained billing and clinical information in the CPR+ computer application, a software system designed specifically for use by specialty pharmacies. The CPR+ system contained tabs that categorized various types of information related to a specific individual's account. With regard to collection information, the CPR+ system contained an online ledger of payments related to a specific account under a payment tab, which indicated the amount of money a patient had paid toward the overall balance.

70. Relators regularly reviewed and reconciled claims submitted to federally funded healthcare programs through the CPR+ system, including with respect to the cost-sharing amounts associated with such claims.

71. In reviewing claims, billing and clinical information on the CPR+ system, Relators identified accounts with cost-sharing balances reflecting unpaid cost-sharing obligations. Relators observed that a high number of accounts, including those billed to federally-funded health care programs, had patient cost-sharing balances, many of which were ultimately written off purportedly based on financial hardship, even though no there was no record of authenticated financial hardship. These accounts included claims that had already been submitted by the Pharmacies for reimbursement, including to federally-funded health care programs, with payment for the claim having been received (at least in part) by the Pharmacies.

72. When Relators identified these unpaid balances and inquired about collection efforts for the cost-sharing obligations, Relators and other Biotek employees were instructed not to mail invoices or otherwise engage in any collection efforts.

73. In many instances, Biotek employees were instructed to falsely make entries next to each unpaid balance in CPR+ to make it appear as though the Pharmacies attempted three collection efforts before writing off the balance. In reality, no collection efforts were made.

74. A substantial number of cost-sharing balances in the CPR+ system were written off purportedly based on financial hardship, when actual financial hardship had not been substantiated.

75. In fact, the Biotek Defendants did not even maintain a standardized process to verify financial hardship. Instead, employees were routinely instructed to send financial hardship forms directly to Defendant Sparkler – the commissioned Chief Marketing Officer of Defendant Biotek – who approved waivers of cost-sharing obligations without engaging in discussion with the patient or otherwise analyzing the patient's financial condition.

76. For example, on February 1, 2019, Defendant Biotek submitted a claim to Express Scripts (Medicare Part D plan) for the IVIG drug, Privigen, which Biotek filled for a Medicare beneficiary referred by E.A. The beneficiary's cost-sharing responsibility for this claim was $1,028.98. Nevertheless, as of August 2019, Defendant Biotek had made no effort to collect any of the beneficiary's past cost-sharing balances, which amounted in total to more than $10,146. When Relators alerted Defendant Sparkler about the cost-sharing balances for this beneficiary, Defendant Sparkler stated that she would sign off on qualifying the beneficiary for full financial hardship and instructed Relators to adjust off the entire cost-sharing balance, by transferring the balance to the Biotek Foundation.

77. In fact, Defendant Sparkler signed off on numerous financial hardship forms in the first half of 2019, without verifying the beneficiaries' financial hardship.

78. In other instances, Defendants Sparkler and Gadde instructed Biotek employees to indicate in the CPR+ system that the patient qualified for financial hardship assistance through the

"Biotek Foundation," through which the cost-sharing obligation was to be paid. A public records search does not reveal any charitable organization under such name. Like other waivers of cost-sharing amounts, these too were made without authentication of financial need.

79. By indicating in the CPR+ system that the patient qualified for financial hardship assistance through the Biotek Foundation, the Biotek Foundation was designated as the responsible payer for the patient cost-sharing balance. Ultimately, the cost-sharing balance was written off without any funds ever being applied to the account.

80. In 2018 alone, the Pharmacies waived $1.8 million in cost-sharing balances, a large percentage of which was for Medicare beneficiaries.

81. By September 2019, Defendant Biotek had over $1.1 million in unpaid patient cost-sharing balances, a substantial percentage of which was for Medicare beneficiaries.

82. The Biotek Defendants' practice of routine waiver of beneficiary cost-sharing was regularly communicated to the Biotek Defendants' employees and marketed externally to clinicians and beneficiaries.

83. Under the direction of Defendant Sparkler in her role as Chief Marketing Officer, the Biotek Defendants maintained a team of commissioned sales representatives, who were responsible for establishing relationships with physicians and patients to obtain referrals to the Pharmacies.

84. As part of the Biotek Defendants' marketing strategy, Defendant Sparkler instructed sales representatives to inform certain physicians and physician practices, including Defendant Tabby, that their patients would not be responsible for cost-sharing if they utilized one of the Pharmacies as their specialty infusion pharmacy.

85. For example, Defendant Biotek maintained a lucrative referral relationship with three neurologists, Defendant Tabby, J.S. and E.A. In order to induce and reward referrals, Defendant Biotek waived cost-sharing obligations for patients referred by Defendant Tabby, J.S. and E.A. without regard to financial hardship.

86. Referral relationships were carefully monitored by the Biotek Defendants. Indeed, a special alert in the CPR+ system flagged referrals by certain physicians, such as Defendant Tabby, J.S. and E.A., and reminded Biotek employees not to invoice referred patients for cost-sharing amounts.

87. For example, in January 2019, Relator Sparrow wrote that a patient referred to Biotek by Defendant Tabby had inquired about receiving financial assistance for a $1,600 copayment associated with an upcoming fill of Gammagard, and noted that Biotek had never invoiced the patient for past copayments because the patient was referred by Defendant Tabby. In response, Defendant Sparkler stated that even though she had no idea who the patient was, the patient should receive financial assistance and that Defendant Tabby would sign off on any paperwork that was necessary.

88. Later, in January 2019, Relator Sparrow wrote to Defendants Gadde and Sparkler to inform them that more than $1.8 million in patient cost-sharing balances remained outstanding in the Pharmacies' accounts receivable. In response to Relator Sparrow's email, Defendant Sparkler referenced the Biotek Defendants' practice of categorically waiving the cost-sharing of patients referred to the Pharmacies by Defendant Tabby, writing that if the balances were for patients previously referred by Tabby, they were to be written off.

89. On a routine basis, Biotek employees, including Relators, answered telephone calls from patients who inquired about why they had not received an invoice from the Pharmacies after

seeing their Explanation of Benefits. Defendants Gadde and Sparkler instructed Biotek employees fielding these inquiries to inform the patient that the patient qualified for full financial hardship assistance through the Biotek Foundation. Nonetheless, in some instances, patients insisted on being invoiced for cost-sharing amounts.

90. During their employment with Defendant Biotek, Relators repeatedly voiced concerns to Defendants Gadde and Sparkler regarding the improper waiver of patient cost-sharing obligations. For example, in or around May 2019, Defendants Gadde and Sparkler convened a meeting of Biotek employees, where Relator Wyatt reported her concerns that patient cost-sharing obligations were improperly and routinely waived. Defendants Gadde and Sparkler dismissed Relator Wyatt's concerns and reiterated that Biotek employees were not to invoice patients for balances owed.

91. The Biotek Defendants' unlawfully induced referrals from physicians by means beyond the routine waiver of cost-sharing obligations. The Biotek Defendants also provided kickbacks to referring physicians and their practices, including Defendant Tabby, in the form of expensive meals and entertainment and through the provision of free administrative, clinical and insurance support to assist in getting claims for Biotek's specialty drugs paid by insurance providers.

92. For example, on multiple occasions, Defendant Sparkler posed as a member of Defendant Tabby's practice and performed peer to peer discussions with insurance companies on behalf of Defendant Tabby in order to get claims for infusion products and services paid.

93. By routinely waiving cost-sharing amounts, without regard to individual circumstances and without *bona fide* authentication of patient financial needs and by providing Defendant Tabby and other referring physicians with expensive meals and entertainment, and free

administrative, clinical and insurance support in exchange for the referral of beneficiaries to Pharmacies the Pharmacies, Defendants knowingly violated the AKS. Accordingly, all claims for payment submitted to federally funded health care programs by the Pharmacies and Defendant Tabby for infusion products and services resulting from these illegal kickbacks are false claims under the federal False Claims Act.

94. The Pharmacies also overbilled Medicare and other federally funded healthcare programs for infusion products above the allowable amount, at times billing double or triple the amount of what was actually provided to the patient.

VI. CLAIMS FOR RELIEF

FIRST COUNT

Violations of False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

95. Relators re-allege and incorporate by reference the allegations of paragraphs 1- 93 of this complaint.

96. This is a claim for treble damages and civil penalties under Section 31 U.S.C. § 3729(a)(1)(A).

97. By virtue of the acts alleged herein, Defendants have knowingly presented or caused to be presented to officers or employees of the United States government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

98. The United States, unaware of the false and fraudulent nature of these claims, paid these claims, which otherwise would not have been paid.

99. By reason of the false or fraudulent claims, the United States has sustained damages, and continues to sustain damages, in a substantial amount.

SECOND COUNT

Violations of False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

100. Relators re-allege and incorporate by reference the allegations of paragraphs 1-93 of this complaint.

101. This is a claim for treble damages and civil penalties under Section 31 U.S.C. §3729(a)(1)(B).

102. By virtue of the acts alleged herein, Defendants have knowingly made, used, or caused to be made or used false records or statements—to include false certifications and representations made or caused to be made by Defendants, to get false or fraudulent claims paid or approved by the government in violation of 31 U.S.C. § 3729(a)(1)(B).

103. By reason of the false or fraudulent claims, the United States has sustained damages, and continues to sustain damages, in a substantial amount.

THIRD COUNT

Violations of False Claims Act, 31 U.S.C. § 3729(a)(1)(C)

104. Relators re-allege and incorporates by reference the allegations of paragraphs 1-93 of this complaint.

105. By virtue of the acts alleged herein, Defendants conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States, 31 U.S.C. §3729(a)(1)(C).

FOURTH COUNT

Violations of False Claims Act, 31 U.S.C. § 3729(a)(1)(G)

106. Relators re-allege and incorporate by reference the allegations of paragraphs 1-93 of this complaint.

107. By virtue of the acts alleged herein, Defendants knowingly concealed and knowingly and improperly avoided an obligation to repay money owed to the United States for specialty infusion drugs that were tainted by kickbacks in violation of 31 U.S.C. § 3729(a)(1)(G).

WHEREFORE, Relators request the following relief:

A. Defendants pay an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty against Defendants of the maximum amount for each violation of 31 U.S.C. § 3729;

B. Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

C. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729, et seq.;

D. Relators be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d);

E. The United States and Relators be granted all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury as to all issues.

DATED, this 10th of March, 2021

Respectfully submitted,

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